K073624 # 1/2

MAR 20 2008

510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

OrthoHelix Surgical Designs, Inc.
1815 W. Market
Akron, Ohio 44313
Phone: (330) 869-9582
Fax: (330) 869-9583

Contact Person: Derek Lewis
Director of Engineering

Date Prepared: 12/17/07

Name of Device

Modular Foot System

Common or Usual Name

Fixation Plates and Screws

Classification Name

Plate, Fixation, Bone

Predicate Devices

Darco Locking Bone Plate System (K061808)
OrthoHelix MaxLock Small Bone System (K050868)

Intended Use

The Modular Foot System is indicated for fractures, fusions and osteotomies of the hand, wrist, foot and ankle in pediatric and adult patients.

K073604 p 2/3

Device Description

The OrthoHelix Modular Foot System is a set of metallic, implantable, bone fixation plates and screws. The System includes 26 fixation plates and 66 screws, which include all different sizes. It also includes various surgical instruments such as drill guides, drill bits and drivers. All screws and plates are made from implant grade titanium, Ti-6Al-4V ELI per ASTM F-136.

Performance Data

Finite Element Analysis, mechanical testing and hand calculations all confirm that the implants within the Modular Foot System are substantially equivalent to its predicate devices, and that it meets the specified requirements for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Orthohelix Surgical Designs, Inc.
% Mr. Derek Lewis
1815 W. Market
Akron, OH 44313

MAR 20 2008

Re: K073624
Trade/Device Name: Modular Foot System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: March 6, 2008
Received: March 6, 2008

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: Modular Foot System

Indications for Use:

The Modular Foot System is indicated for the fractures, fusions and osteotomies for small bones in the hand, wrist, foot and ankle in both pediatric and adult patients.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073624